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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,422	07/24/2001	Jean Paul Remon	522-1741	4232

7590 10/22/2003

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	12

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,422	REMON, JEAN PAUL	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,40,42-44 and 46-60* is/are pending in the application.

4a) Of the above claim(s) *1-38,41 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39,40,42-44 and 46-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Response filed on May 5, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39, 40, 42-44 and 46-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang (US 4590062) in combination with Khan et al. (US 5656296). Jang teaches a controlled release tablet formulation comprising an active agent and a combination of a hydrophobic cellulose derivative, a fatty acid material or a neutral lipid and a wax (Col. 3, lines 1-62). The components of the tablet are dry compressed together to produce a controlled release tablet. The active agent of the composition can be any substance when administered into the body of a human, animal, plant, soil and water is biologically active in a therapeutic sense (Col. 4, line 36 – Col. 6, line 19). The

waxes of the composition have melting points from 50° to 100° C and are chosen from carnauba wax, spermaceti, beeswax, candelilla wax, esparto, and paraffin wax (Col. 3, lines 44-48; Col. 7, lines 27-41). The wax is present in the matrix composition up to 99 wt% (Col. 7, lines 27-41).

The teachings of Jang do not include a specific example of the embodiment of the instant claims. Jang does give concentration ranges of each of the components that do at least overlap with the concentration of the instant claims. Jang further does not teach the exact formulation for the active beads or particles.

Khan teaches active cores or particles that comprise a core of an active and a wax that is further coated to produce a sustained release formulation (Col. 2, lines 45-65). Khan recites various suitable pharmaceuticals that can be present in the drug cores (Col. 3, line 14 – Col. 4, line 50). The wax contained in the core can be natural or synthetic (Col. 4, line 51 – Col. 6, line 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of active agent as well as the amounts of wax present in the controlled release formulation of the Jang reference. While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, it would have been obvious to include as the

active cores of Jang, the particles taught by the Khan reference. Finally, it is the position of the Examiner that the prior art teaches the waxes suitable for the instant claims and no criticality is seen in the new limitations of carbon chain length for the microcrystalline hydrocarbon waxes.

One of ordinary skill in the art would have been motivated to do this to prepare controlled release formulations for various active agents for humans, animals and plants, where in the amount of active agent can change the amount of wax and other excipients need for the controlled release system. Further, the amount of wax and additional ingredients will vary depending on the desired release rate or profile to be achieved. The expected result is a tablet formulation with an active agent and a wax component that achieves a controlled release profile.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed May 5, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art does not teach a formulation containing coated cores and wax beads wherein the wax beads are cushioning beads. The prior art teaches an active particle that is dry mixed with wax particles and compressed into tablets. The secondary reference teaches coated cores that can be compressed into tablet formulations for controlled release profiles. It is the position of the Examiner that would be obvious to include the coated beads/cores in the formulation of Jang wherein you would have a coated active core with a wax particles

that are dry mixed and compressed into tablets. Whether you call the wax component particles or cushioning bead is no of consequence. You will still have a tablet comprising an active coated core with wax particle that were dry mixed and compressed to form tablets. Applicants have provided no superior or unexpected results over the prior art with the particular limitations recited in the instant claims. Absent a showing of unexpected results, applicants' instant claims are rendered obvious by the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703)

308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
October 20, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600